

# EXHIBIT B


**UNITED STATES DEPARTMENT OF COMMERCE**  
**Patent and Trademark Office**

 Address : COMMISSIONER OF PATENTS AND TRADEMARKS  
 Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
---------------	-------------	----------------------	---------------------

07/800,549 11/27/91 OSHLACK

B 91-318

EXAMINER

SPEAR, J

ART UNIT

PAPER NUMBER

1502

2

DATE MAILED: 04/30/92

 STEINBERG & RASKIN  
 1140 AVENUE OF THE AMERICAS  
 NEW YORK, NY 10036

 This is a communication from the examiner in charge of your application.  
 COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 11-27-1991 ☐ This action is made final.

 A shortened statutory period for response to this action is set to expire 3 month(s), \_\_\_\_\_ days from the date of this letter.  
 Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

- |   |  |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948.                   |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.                 | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474.     | 6. <input type="checkbox"/> _____  |

**Part II SUMMARY OF ACTION**

1. ☒ Claims 1-17 are pending in the application.  
 Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☒ Claims 1-17 are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_ has (have) been ☐ approved by the examiner ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on \_\_\_\_\_, has been ☐ approved ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received  
☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 193 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINE

Serial No. 800,549

-2-

Art. Unit. 1502

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-17 are rejected under 35 U.S.C. § 103 as being unpatentable over Goldie et al. U.S. 4,990,341 in view of Oshlack U.S. 4,861,598.

Goldie et al. teaches a controlled release oral dosage form of an analgesic, hydromorphone, wherein the active ingredient is in a controlled release matrix. See claim 1. Goldie further teaches peak plasma levels attained between 2.25 and 3.75 hours per claim 4. The reference further teaches dosage ranges which are the same as those of applicants. Conventional matrix forming materials are disclosed in columns 3 and 4. Coating materials are shown at col. 4, lines 37-45. Conventional granulation processes are disclosed in the Examples. Although Goldie does not use oxycodone, both oxycodone and hydromorphone being

Serial No. 800,549

-3-

Art Unit 1502

derivatives of natural alkaloids with many structural similarities are considered interchangeable in the matrix compositions.

Oshlack is relied on for teaching matrix composition as those of applicants' wherein the active agent is oxycodone. See Example II. Claim 1.

It would have been obvious to one of ordinary skill in the art to use oxycodone in the Goldie et al. invention. The motivation to do so is suggested by a desirability to provide optimum drug bioavailability by controlled release from a matrix composition.

Claims 1-17 are rejected.

Any inquiry concerning this communication should be directed to James M. Spear at Telephone number (703) 308-2351.

2

J. Spear/mbb  
April 27, 1992

THOMAS A. PRICE  
SUPERVISORY PATENT EXAMINER  
ART UNIT 152

TO SEPARATE .D TOP AND BOTTOM EDGES, SNAP-APART AND DISCARD CARBON

FORM PTO-892 (REV. 3-78)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		SERIAL NO. <b>800549</b>	GROUP/ART UNIT <b>1502</b>	ATTACHMENT TO PAPER NUMBER <b>2</b>			
NOTICE OF REFERENCES CITED				APPLICANT(S) <b>OSHLACK et al.</b>					
U.S. PATENT DOCUMENTS									
*		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE		
	A	<b>4861598</b>	<b>8-89</b>	<b>Oshlack</b>	<b>424</b>	<b>470</b>	<b>/</b>		
	B	<b>4990341</b>	<b>2-91</b>	<b>Goldie et al.</b>	<b>424</b>	<b>484</b>	<b>(4-89)</b>		
	C								
	D								
	E								
	F								
	G								
	H								
	I								
	J								
	K								
FOREIGN PATENT DOCUMENTS									
*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS	PERTINENT SHTS. DWG.	PP. SPEC.
	L								
	M								
	N								
	O								
	P								
	Q								
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)									
	R								
	S								
	T								
	U								
EXAMINER <b>James M. Spear</b>				DATE <b>4-18-92</b>					
* A copy of this reference is not being furnished with this office action. (See Manual of Patent Examining Procedure, section 707.05 (a).)									